

63761-3, 63761-5 & 63761-6: Pending Label Notifications Dated March 9, 2010

Wendy McCombie

to:

Tracy Lantz

03/24/2010 11:08 AM

Cc:

Velma Noble

Show Details

Tracy:

I would like to give you a call sometime this afternoon if you are available to discuss the pending label notifications for EPA Reg. Nos. 63761-3, 63761-5 and 63761-6. These Notifications were recently submitted and dated March 9, 2010.

After we received the January 28, 2010 Agency rejection letter for the 63761-3, we revised the 63761-3, 63761-5 and 63761-6 labels to add the container disposal language for the actual disposal of the container itself per the aforementioned letter. We also modified the arrangement and added notes to the reviewer for the triple rinse and pressure rinse instructions to provide better clarification on container sizes and an option to omit the pressure rinse instructions since the pressure rinsing is optional per the Residue Removal Statements in Appendix B of PR Notice 2007-4 as either "Triple rinse or pressure rinse container (or equivalent) promptly after emptying" or "Triple rinse container (or equivalent) promptly after emptying'."

Following submission of the March 9, 2010 Notifications for 63761-3, 63761-5 and 63761-6, we received the March 2, 2010 letters (on March 18th and March 19th) for the 63761-5 and 63761-6 which included additional comments that did not appear in the letter January 28, 2010 Agency rejection letter for the 63761-3. One of these comments was to indicate "nonrefillable containers" in the note to reviewer. We believe that it is clear from the very first sentence in the CONTAINER DISPOSAL section that states "Nonrefillable container" that the containers are all non-refillable containers, and the inclusion of "nonrefillable container" in the note to reviewer would not be necessary (since it s already previously stated). However, if this verbiage is necessary in the note to reviewer in order for the labels to clear the review process, we can add it and would like to submit such a revision by e-mail to replace the labels for the March 9, 2010 Notifications. We believe this would help save time for both the Agency and the Registrant instead of having to go back and forth with rejection letters and

resubmissions, as the Registration Division has been doing this with regard to minor issues for the PR Notice 2007-4 submissions.

The March 2, 2010 letter for the 63761-6 also indicates an issue with the residue removal instructions. We hope that the March 9, 2010 Notification labels help clarify the situation with regard to pressure rinse and triple rinse. Again, the Residue Removal Statements in Appendix B of PR Notice 2007-4 are listed as either "Triple rinse or pressure rinse container (or equivalent) promptly after emptying' or 'Triple rinse container (or equivalent) promptly after emptying'." Sterilex would like to have pressure rinsing an optional language for the labels, since it is not always feasible for certain container sizes.

For the 63761-5, the March 2, 2010 letter we just received (the March 9, 2010 Notification was submitted before the rejection letter arrived) the indicated that there is an issue with the "Precleaning Whirlpool Bathtubs" use rate. Sterilex has indicated that the 50g use for pre-cleaning previously listed on the label accepted July 14, 2008 was a typographical error. If the Agency would review the other "Precleaning" instructions on the label in the other sections, it is indicated as 1-25 g, not 50 g. The 50g use rate is for disinfection purposes only. The non-pesticidal Precleaning instructions are not for disinfection purposes but to remove gross filth or soil. The directions for use under the "Precleaning Whirlpool Bathtubs" should match the other "Precleaning" instructions on the label, which is 1-25 g throughout.

As previously stated, I believe it would help both the Agency and the Registrant to replace the labels for the pending March 9, 2010 Notifications for 63761-3, 63761-5 and 63761-6 by e-mailing PDFs of the labels with any requested revisions rather than a continual back-and-forth of rejection letters and resubmissions as new comments crop up. I am hoping the Agency can cooperate in this effort to save both time and money for both parties.

If there is a preferred time for me to call this afternoon, please let me know and I can work with your schedule.

Thank you in advance for your help, Tracy.

Best regards,

Wendy A. McCombie
Lewis & Harrison, LLC
122 C Street NW, Suite 740
Washington, DC 20001
202-393-3903x11 (phone)
202-393-3906 (fax)
wmccombie@lewisharrison.com (e-mail)

This e-mail message contains confidential or privileged information intended solely for the addressee. Please do not read, copy, or disseminate it unless you are the recipient specified for this message. If you have received it in error, please call us at (202) 393-3903 and ask to speak with the message sender. Also, we would appreciate it if you could forward the message back to us and delete it from your system. Thank you for your cooperation.